chapter governing fixed combination prescription drugs for humans.

(f) New drug applications have been received from persons marketing orally administered single entity amphetamine or dextroamphetamine dosage forms. Any other person who intends to market such drug is required to submit to the Food and Drug Administration an abbreviated application under §314.55 of this chapter.

(g) The labeling conditions for single entity oral dosage forms of amphetamine and dextroamphetamine and their salts are as follows:

(1) The label shall bear the statement ''Caution: Federal law prohibits dispensing without prescription''.

(2) The drug shall be labeled to comply with all requirements of the act and regulations. The labeling shall bear adequate information for safe and effective use of the drug. The indications for use are:

Narcolepsy.

Minimal brain dysfunction in children (hyperkinetic behavior disorders), as an aid to general management.

Management of exogenous obesity as short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to other measures.

(3) Complete labeling guidelines are available from the Food and Drug Administration.

(h) Regulatory proceedings will be initiated with regard to any such drug within the jurisdiction of the act which is not in accord with this regulation.

[39 FR 11680, Mar. 29, 1974, as amended at 41 FR 10885, Mar. 15, 1976; 55 FR 11578, Mar. 29, 1990]

§310.506 Use of vinyl chloride as an ingredient, including propellant, of aerosol drug products.

(a) Vinyl chloride has been used as a propellant in aerosol drug preparations. Evidence indicates that vinyl chloride inhalation can result in acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness where inhaled at high concentrations. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have been reported in animals. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Recently, vinyl chloride has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride.

(b) The Commissioner finds that there is a lack of general recognition by qualified experts of the safety or effectiveness of aerosol drug preparations containing vinyl chloride as an ingredient, including propellant. Therefore, any such product containing vinyl chloride is a new drug and a new drug application approved under section 505 of the Federal Food, Drug, and Cosmetic Act is required for marketing.

(c) Clinical investigations designed to obtain evidence that any aerosol drug preparation containing vinyl chloride as an ingredient, including propellant, is safe and effective for the purpose intended, must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) Any such drug within the jurisdiction of the act which is not in accord with this regulation is subject to regulatory action.

[39 FR 30830, Aug. 26, 1974, as amended at 55 FR 11578, Mar. 29, 1990]

§310.507 Aerosol drug products for human use containing 1,1,1-trichloroethane.

(a) Trichloroethane has been used in aerosol drug products as a solvent for the active ingredients and to reduce the vapor pressure of the propellants. It is potentially toxic to the cardiovascular system, i.e., can sensitize the heart to epinephrine. At a sufficiently large concentration, it is a potent anesthetic agent. Deaths associated with aerosol decongestant products intended to be inhaled and containing trichloroethane have been reported. Most of the deaths resulted from abuse or gross misuse of the preparations.

(b) The Food and Drug Administration finds that there is a lack of general recognition by qualified experts of the safety or effectiveness of trichloroethane in aerosol drug products intended for inhalation either directly or indirectly. Any aerosol drug product containing trichloroethane and labeled, represented, or advertised for

use by inhalation is a new drug and subject to regulatory proceedings unless it is the subject of a new drug application approved pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act.

(c) Clinical investigations designed to obtain evidence that any aerosol drug product containing trichloroethane and labeled, represented, or advertised for use by inhalation either directly or indirectly is safe and effective for the purposes intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) Regulatory proceedings will be initiated with regard to any such drug within the jurisdiction of the act which is not in accord with this regulation on January 16, 1978.

[42 FR 63387, Dec. 16, 1977, as amended at 55 FR 11578, Mar. 29, 1990]

§ 310.508 Use of certain halogenated salicylanilides as an inactive ingredient in drug products.

(a) Halogenated salicylanilides (tribromsalan (TBS, 3,4′,5–tribromosalicylanilide), dibromsalan (DBS, 4′, 5–dibromosalicylanilide), metabromsalan (MBS, 3, 5–dibromosalicylanilide), and 3,3′, 4,5′–tetrachlorosalicylanilide (TC–SA)) have been used as active or inactive ingredients in a number of over-the-counter (OTC) drug products, largely antibacterial soaps, for antimicrobial, preservative, and other purposes. These halogenated salicylanilides are potent photosensitizers and can cause disabling skin disorders. In some instances the photosensitization may persist for prolonged periods as a severe reaction without further exposure to these chemicals. Safer alternative antimicrobial agents are available.

(b) These halogenated salicylanilides are not generally recognized as safe and effective for use as active or inactive ingredients in any drug products. Therefore, any drug product containing such a halogenated salicylanilide as an ingredient at any level for any purpose is a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act for which an approved new drug application pursuant to section 505 of the act and part 314 of this chapter is required for marketing.

(c) Clinical investigations designed to obtain evidence that any drug product containing a halogenated salicylanilide as an ingredient at any level for any purpose is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) Any such drug product initially introduced into interstate commerce after December 1, 1975, that is not in compliance with this section is subject to regulatory action.

[40 FR 50530, Oct. 30, 1975, as amended at 55 FR 11578, Mar. 29, 1990]

§ 310.509 Parenteral drug products in plastic containers.

(a) Any parenteral drug product packaged in a plastic immediate container is not generally recognized as safe and effective, is a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, and requires an approved new drug application as a condition for marketing. A ''Investigational New Drug Application'' set forth in part 312 of this chapter is required for clinical investigations designed to obtain evidence of safety and effectiveness.

(b) It is common medical practice to add various drugs to containers of large volume parenteral drug products for single administration to the patient, although in many cases the safety and effectiveness of that practice has not been demonstrated. Accordingly the Commissioner of Food and Drugs concludes that reports of a full investigation of the compatibility of the immediate container of certain large volume parenteral drugs with certain other drugs that may be added regularly to the parenteral delivery system is necessary under section 505(k) of the act to determine whether there is ground for requiring revision of the labeling to provide for safer use of the large volume parenteral drug products or ground for withdrawing approval, under section 505(e) of the act, of any of the approved new drug applications for the products. As used in